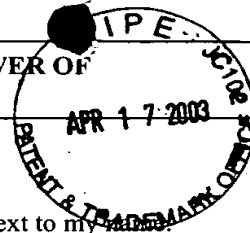


COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)

Attorney's Docket Number:
5866.200-US



As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Dry Mouldable Drug Formulation

The specification of which (check only one item below):

☐ is attached hereto

☒ was filed as United States application

Application No. 09/550,857

on April 17, 2000

and was amended

on _____

☐ was filed as PCT international application

Number _____

on _____

and was amended under PCT Article 19

on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by an amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISIONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicated "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119	
US	60/139,403	14 June, 1999	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Denmark	PA 1999 00514	16 April, 1999	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

Attorney's Docket Number:

5866.200-US**(Includes Reference to PCT International Applications)**

I hereby claim the benefit under Title 35, United States Code '120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, '112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, '1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned
PCT APPLICATIONS DESIGNATING THE U.S.				
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)		

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. Reza Green Richard W. Bork Marc A. Began Rosemarie R. Wilk-Orescan
Reg. No. 38,475 Reg. No. 36,459 Reg. No. 48,829 Reg. No. 45,220

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Changed 26 Feb 2003

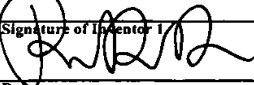
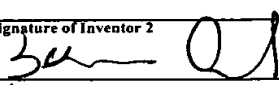

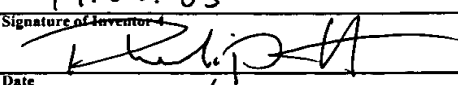
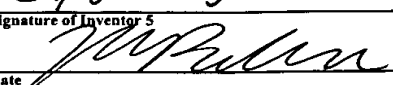
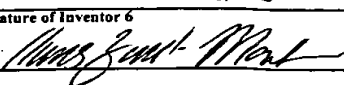
COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number:

5866.200-US

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	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
8	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
9	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1 	Signature of Inventor 2 	Signature of Inventor 3 
Date 19.02.03	Date 27/3-2003	Date 26 Feb 2003
Signature of Inventor 4 	Signature of Inventor 5 	Signature of Inventor 6 
Date 27/3-2003	Date 20-2-03	Date 24-03-2003
Signature of Inventor 7	Signature of Inventor 8	Signature of Inventor 9
Date	Date	Date



#17
4-22-03
[Signature]

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Thomas Buch-Rasmussen, Søren Aasmul, Jens-Ulrik Poulsen, James M. Flink,
Philip Hansen and Claus Juul-Mortensen
Serial No.09/550,857
Filed: April 17, 2000 Examiner: Josephine Young
Title: Dry, mouldable drug formulation

DECLARATION OF THOMAS BUCH-RASMUSSEN, UNDER 37 C.F.R. § 1.132

I, Thomas Buch-Rasmussen declare and state as follows:

34. I am employed by Novo Nordisk A/S, Denmark in the position of Manager. I received a Master Degree from the Technical University of Denmark (DTU) in 1987 in the field of chemistry. I also hold a Nordic Industrial Research degree from 1989 in the field of Biosensors.
35. Upon graduating from DTU, I was employed by Radiometer Medical in the field of Biosensors. Such work involved Analytical chemistry, Electrochemistry and Material Science. From 1990 to present, I am employed by Novo Nordisk A/S in the capacity of Research scientist, project Manager and Manager. Such work involved Analytical chemistry and Material science within the Medical Device field.
3. I am co-inventor on the above-identified U.S. application. I have reviewed the Office Action of 19 November 2002.
4. Amended claim 1 of US application No.09/550,857 as amended 3 May 2002 recites a pharmaceutical composition having the shape of a needle capable of penetrating cutis or mucosa, comprising at least 0.5% carbohydrate binder and at least 25% of a therapeutical agent as well as one non-crystallisation agent.
5. I have read and understood patent application WO 96/03978 by Roser et al.
6. Roser et al. describes a pharmaceutical composition of a glassy matrix comprising a guest substance that may be a drug. The glassy matrix may comprise hydrophobically derivatized carbohydrates (HDC). The composition may be in the form of for example a powder of microneedles or microfibre or in the form of a needle.

Roser et al. does nowhere describe a pharmaceutical composition as described in claim 1 of the present invention.

Even though Roser et al. states that more than 20% organic molecules can be incorporated into an HDC melt, the document is silent about what the ratio between HDC and organic molecule must be in order to obtain a needle of sufficient strength to penetrate cutis or mucosa.

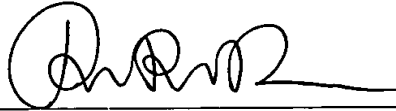
The only example describing the preparation of a macroscopic needle of HDC, describes a needle of a hollow fibre of 100% HDC. The cavity of said fibre contains an HDC powder comprising a drug.

It is apparent to a person skilled in the art that HDC mixed with most common drugs will be less strong than HDC alone. It is not clear from Roser et al. what the threshold of drug allowable in a composition is in order to obtain a needle with sufficient intrinsic strength.

Hence, based on Roser et al. a person skilled in the art would not have reached at the invention as described in the above-mentioned application.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 17.02 2003

Signature: 
(Thomas Buch-Rasmussen)